

Docket No.: 220243US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF: : EXAMINER: DAVIS, Z.N.
STEPHEN ARKINSTALL ET AL : GROUP ART UNIT: 1625
SERIAL NO.: 10/088,074 : U.S. PATENT NO.: 7,432,286
FILED: OCTOBER 13, 2004 : ISSUED: OCTOBER 7, 2008
FOR: PHARMACEUTICALLY ACTIVE SULFONYL HYDRAZIDE DERIVATIVES

PETITION UNDER 37 C.F.R. §1.705(d) AND
REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

SIR:

Petitioners hereby request reconsideration of the final patent term adjustment for U.S. Patent No. 7,432,286 ("the '286 patent") of 601 days and, in place thereof, Petitioners request that the patent term adjustment be changed to 922 days.

Petitioners contend that the Office erred in determining patent term adjustment published on the face of the '286 patent by not properly accounting for the period of time where issuance of the '286 patent was delayed beyond three years of pendency (35 U.S.C. §154(b)(1)(B)).

Correction of the foregoing error in the patent term adjustment is requested in view of the present Petition including the facts and remarks that follow

Patent Term Adjustment indicated in the Notice of Allowance and on the '286 Patent:

On June 25, 2008, a Notice of Allowance was issued in U.S. Application Serial No. 10/088,074, which indicated that the determination of patent term adjustment under 35 U.S.C. §154(b) was 601 days. This patent term adjustment was calculated as the sum of (a) the 562-day period in which the Office failed to mail of either an action under 35 U.S.C. §132, or a notice of allowance under 35 U.S.C. §151 following expiration of 14 months from filing (37 C.F.R. §1.703(a)(1)) and (b) the 39-day period in which the Office failed to act starting four months after the date a reply in compliance with 37 C.F.R. §1.113(c) was filed and ending on the date of mailing of a notice of allowance under 35 U.S.C. §151 (37 C.F.R. §1.703(a)(1)).

On October 7, 2008, the Office issued U.S. 7,432,286. On the face of the '286 patent a patent term adjustment of 601 days is indicated.

Statute relevant to decision on Petition:

35 U.S.C. §154(b) provides for the patent term guarantees giving rise to an adjustment in patent term.

Specifically, 35 U.S.C. §154(b)(1) provides for the following adjustments to the patent term:

(1) PATENT TERM GUARANTEES.-

(A) GUARANTEE OF PROMPT PATENT AND TRADEMARK OFFICE RESPONSES.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to-

(i) provide at least one of the notifications under section 132 of this title or a notice of allowance under section 151 of this title not later than 14 months after-

the date on which an application was filed under section 111(a) of this title; or

the date on which an international application fulfilled the requirements of section 371 of this title;

- (ii) respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken;
- (iii) act on an application within 4 months after the date of a decision by the Board of Patent Appeals and Interferences under section 134 or 135 or a decision by a Federal court under section 141, 145, or 146 in a case in which allowable claims remain in the application; or
- (iv) issue a patent within 4 months after the date on which the issue fee was paid under section 151 and all outstanding requirements were satisfied, the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION

PENDENCY.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including-

- (i) any time consumed by continued examination of the application requested by the applicant under section 132(b);
- (ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal court; or
- (iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C), the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

(C) GUARANTEE OR ADJUSTMENTS FOR DELAYS DUE TO

INTERFERENCES, SECRECY ORDERS, AND APPEALS.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to-

- (i) a proceeding under section 135(a);
- (ii) the imposition of an order under section 181; or

- (iii) appellate review by the Board of Patent Appeals and Interferences or by a Federal court in a case in which the patent was issued under a decision in the review reversing an adverse determination of patentability, the term of the patent shall be extended 1 day for each day of the pendency of the proceeding, order, or review, as the case may be.

Countering this period is the limitations enunciated in 35 U.S.C. §154(b)(2), which sets forth:

(2) LIMITATIONS.-

(A) IN GENERAL.- To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

(B) DISCLAIMED TERM.- No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.

(C) REDUCTION OF PERIOD OF ADJUSTMENT.-

- (i) The period of adjustment of the term of a patent under paragraph (1) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.
- (ii) With respect to adjustments to patent term made under the authority of paragraph (1)(B), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.
- (iii) The Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.

Grounds for Request for Reconsideration and Reinstatement of Patent Term Adjustment:

At issue in this case is the Office's misapplication of the provision in 35 U.S.C. §154(b)(2) that states "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed."

On the face of the '286 patent a patent term adjustment of 601 days is indicated. The Office determination of the 601-day patent term adjustment is in error in that, pursuant to 35 U.S.C. § 154(b)(1)(B), the Office failed to properly allow an adjustment for the time exceeding three years after the actual filing date of the present application (October 13, 2004) to the date when the '286 patent issued (October 7, 2008). The correct patent term adjustment for the '286 patent is 922 days.

In this case, the period of patent term adjustment under 35 U.S.C. §154(b)(1)(A) and 35 U.S.C. §154(b)(1)(B) are calculated independently. The following is a summary of the time periods and the number of days of PTA:

35 U.S.C. §154(b)(1)(A)

- (a) **Plus 562 days** from December 13, 2004 (i.e., 14 months from the filing date of October 13, 2004) to June 28, 2007 when Office mailed a Restriction Requirement (i.e., an action under 35 U.S.C. §132) (35 U.S.C. §154(b)(1)(A)(i) and 37 C.F.R. §1.703(a)(1)); and
- (b) **Plus 39 days** from May 17, 2008 (i.e., 4 months from Petitioners' response to Non-Final Office Action) to June 25, 2008 when the Office mailed a notice of allowance under 35 U.S.C. §151 (35 U.S.C. §154(b)(1)(A)(ii) and 37 C.F.R. §1.703(a)(1));

TOTAL patent term adjustment under 35 U.S.C. §154(b)(1)(A) = **601 days**.

35 U.S.C. §154(b)(1)(B)

Plus 360 days from October 13, 2007 (i.e., 3 years from the filing date of October 13, 2004) to October 7, 2008 when the present application issued as the '286 patent. No RCE was filed.

TOTAL patent term adjustment under 35 U.S.C. §154(b)(1)(B) = **360 days**.

35 U.S.C. §154(b)(2)(C) correction

Minus 0 days due to Petitioners' failure to engage in reasonable efforts to conclude prosecution of the application (35 U.S.C. §154(b)(2)(C) and 37 C.F.R. §1.704(a)).

35 U.S.C. §154(b)(2) states "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed."

In *Wyeth v. Dudas*, Civil Action No. 07-1492 (JR) (2008 U.S. Dist. Lexis 76063 (D.D.C., September 30, 2008), copy **enclosed herewith**, the Court issued an opinion explaining the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b).

Specifically, when determining the overlap defined in 35 U.S.C. §154(b)(2), the *Wyeth* Court held that "[t]he only way that [A and B] periods of time can 'overlap' is if they occur on the same day" (see page 3, left column, first fully paragraph). In other words, the A delay (i.e., delay under 35 U.S.C. §154(b)(1)(A)) and B delay (i.e., delay under 35 U.S.C. §154(b)(1)(B)) only overlap if the A delay occurs after three years of pendency.

With this proper frame of reference, Petitioners return to the calculation above. In this case, the A delay and the B delay overlap from May 17, 2008 to June 25, 2008 (**39 days**). Accordingly, this period of overlap is discounted from the combined total of the A delay and the B delay. The resulting calculation of the patent term adjustment for the '286 patent should be as follows:

A delay		B delay		35 U.S.C. §154(b)(2) correction		Applicant Delay		Total PTA
601	+	360	-	39	-	0	=	922

In view of the foregoing and supported by *Wyeth v. Dudas*, Petitioners respectfully request that the Office correct the error in the patent term adjustment for the '286 patent and properly indicate that the patent term adjustment has been changed to 922 days.

In accordance with the provisions of 37 C.F.R. §1.704(b) and (d), Petitioners submit herewith the requisite fee under 37 C.F.R. §1.18(e). In the event that the Office determines that additional fees are required, it is requested that any underpayment be charged to their undersigned Representative's deposit account (Deposit Account No. 15-0030).

For the foregoing reasons, Petitioners respectfully submit that the Request for Reconsideration of the Patent Term Adjustment of U.S. 7,432,286 should be GRANTED and the patent term adjustment should properly be indicated as 922 days. Early notification of such action is earnestly solicited.

Respectfully submitted,

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WYETH v. Dudas
Civil Action No. 07-1492 (JR)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

2008 U.S. Dist. LEXIS 76063 (D.D.C., September 30, 2008)

OPINION BY: JAMES ROBERTSON

MEMORANDUM OPINION

Plaintiffs here take issue with the interpretation that the United States Patent and Trademark Office (PTO) has imposed upon 35 U.S.C. § 154, the statute that prescribes patent terms. Section 154(a)(2) establishes a term of 20 years from the day on which a successful patent application is first filed. Because the clock begins to run on this filing date, and not on the day the patent is actually granted, some of the effective term of a patent is consumed by the time it takes to prosecute the application. To mitigate the damage that bureaucracy can do to inventors, the statute grants extensions of patent terms for certain specified kinds of PTO delay, 35 U.S.C. § 154(b)(1)(A), and, regardless of the reason, whenever the patent prosecution takes more than three years, 35 U.S.C. § 154(b)(1)(B). Recognizing that the protection provided by these separate guarantees might overlap, Congress has forbidden double-counting: "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). Plaintiffs claim that the PTO has misconstrued or misapplied this provision, and that the PTO is denying them a portion of the term Congress has provided for the protection of their intellectual property rights.

Statutory Scheme

Until 1994, patent terms were 17 years from the date of issuance. *See* 35 U.S.C. § 154 (1992) ("Every patent shall contain . . . a grant . . . for the term of seventeen years . . . of the right to exclude others from making, using, or selling the invention throughout the United States. . . ."). In 1994, in order to comply with treaty obligations under the General Agreement on Tariffs and Trade (GATT), the statute was amended to provide a 20-year term from the date on which the application is first filed. *See* Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994). In 1999, concerned that extended prosecution delays could deny inventors substantial portions of their effective patent terms under the new regime, Congress enacted the American Inventors Protection Act, a portion of which -- referred to as the Patent Term Guarantee Act of 1999 -- provided for the adjust-

ments that are at issue in this case. Pub. L. No. 106-113, §§ 4401-4402, 113 Stat. 1501, 1501A-557 (1999).

As currently codified, 35 U.S.C. § 154(b) provides three guarantees of patent term, two of which are at issue here. The first is found in subsection (b)(1)(A), the "[g]uarantee of prompt Patent and Trademark Office response." It provides a one-day extension of patent term for every day that issuance of a patent is delayed by a failure of the PTO to comply with various enumerated statutory deadlines: fourteen months for a first office action; four months to respond to a reply; four months to issue a patent after the fee is paid; and the like. *See* 35 U.S.C. § 154(b)(1)(A)(i)-(iv). Periods of delay that fit under this provision are called "A delays" or "A periods." The second provision is the "[g]uarantee of no more than 3-year application pendency." Under this provision, a one-day term extension is granted for every day greater than three years after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO. ¹ *See* 35 U.S.C. § 154(b)(1)(B). The period that begins after the three-year window has closed is referred to as the "B delay" or the "B period". ("C delays," delays resulting from interferences, secrecy orders, and appeals, are similarly treated but were not involved in the patent applications underlying this suit.)

1 Certain reasons for exceeding the three-year pendency period are excluded, *see* 35 U.S.C. § 154(b)(1)(B)(i)-(iii), as are periods attributable to the applicant's own delay. *See* 35 U.S.C. § 154(b)(2)(C).

The extensions granted for A, B, and C delays are subject to the following limitation:

(A) In general.--To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). This provision is manifestly intended to prevent double-counting of periods of delay, but understanding that intent does not answer the question of what is double-counting and what is not. Proper

interpretation of this proscription against windfall extensions requires an assessment of what it means for "periods of delay" to "overlap."

The PTO, pursuant to its power under 35 U.S.C. § 154(b)(3)(A) to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments," has issued final rules and an "explanation" of the rules, setting forth its authoritative construction of the double-counting provision. The rules that the PTO has promulgated essentially parrot the statutory text, *see* 37 C.F.R. § 1.703(f), and so the real interpretive act is found in something the PTO calls its Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. § 154(b)(2)(A), which was published on June 21, 2004, at 69 Fed. Reg. 34238. Here, the PTO "explained" that:

the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), *the entire period during which the application was pending before the Office* (except for periods excluded under 35 U.S.C. § 154 (b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, *is the relevant period under 35 U.S.C. § 154 (b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).*

69 Fed. Reg. 34238 (2004) (emphasis added). In short, the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for "A delay" or for "B delay," whichever is larger, but never A + B.

In the plaintiffs' submission, this interpretation does not square with the language of the statute. They argue that the "A period" and "B period" overlap only if they occur on the same calendar day or days. Consider this example, proffered by plaintiff: A patent application is filed on 1/1/02. The patent issues on 1/1/08, six years later. In that six-year period are two "A periods," each one year long: (1) the 14-month deadline for first office action is 3/1/03, but the first office action does not occur until 3/1/04, one year late; (2) the 4-month deadline for patent issuance after payment of the issuance fee is 1/1/07, but the patent does not issue until 1/1/08, another year of delay attributable to the PTO. According to plaintiff, the "B period" begins running on 1/1/05, three years after the patent application was filed, and ends

three years later, with the issuance of the patent on 1/1/08. In this example, then, the first "A period" does not overlap the "B period," because it occurs in 2003-04, not in 2005-07. The second "A period," which covers 365 of the same days covered by the "B period," does overlap. Thus, in plaintiff's submission, this patent holder is entitled to four years of adjustment (one year of "A period" delay + three years of "B period" delay). But in the PTO's view, since "the entire period during which the application was pending before the office" is considered to be "B period" for purposes of identifying "overlap," the patent holder gets only three years of adjustment.

Chevron Deference

We must first decide whether the PTO's interpretation is entitled to deference under *Chevron v. NRDC*, 467 U.S. 837, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984). No, the plaintiffs argue, because, under the Supreme Court's holdings in *Gonzales v. Oregon*, 546 U.S. 243, 126 S. Ct. 904, 163 L. Ed. 2d 748 (2006), and *United States v. Mead Corp.*, 533 U.S. 218, 121 S. Ct. 2164, 150 L. Ed. 2d 292 (2001), Congress has not "delegated authority to the agency generally to make rules carrying the force of law," and in any case the interpretation at issue here was not promulgated pursuant to any such authority. *See Gonzales*, 546 U.S. at 255-56, *citing Mead*, 533 U.S. at 226-27. Since at least 1996, the Federal Circuit has held that the PTO is not afforded *Chevron* deference because it does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency. *See Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996).

Here, as in *Merck*, the authority of the PTO is limited to prescribing "regulations establishing *procedures* for the application for and determination of patent term adjustments under this subsection." 35 U.S.C. § 154(b)(3)(A) (emphasis added). Indeed, a comparison of this rulemaking authority with the authority conferred for a different purpose in the immediately preceding section of the statute makes it clear that the PTO's authority to interpret the overlap provision is quite limited. In 35 U.S.C. § 154(b)(2)(C)(iii) the PTO is given the power to "prescribe regulations establishing the *circumstances that constitute* a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application" (emphasis added) -- that is, the power to elaborate on the meaning of a particular statutory term. No such power is granted under § 154(b)(3)(A). *Chevron* deference does not apply to the interpretation at issue here.

Statutory Construction

Chevron would not save the PTO's interpretation, however, because it cannot be reconciled with the plain

text of the statute. If the statutory text is not ambiguous enough to permit the construction that the agency urges, that construction fails at *Chevron's* "step one," without regard to whether it is a reasonable attempt to reach a result that Congress might have intended. See, e.g., *MCI v. AT&T*, 512 U.S. 218, 229, 114 S. Ct. 2223, 129 L. Ed. 2d 182 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear.").

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether "periods of delay attributable to grounds specified in paragraph (1) overlap." The only way that periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day. Recognizing this, the PTO defends its interpretation as essentially running the "period of delay" under subsection (B) from the filing date of the patent application, such that a period of "B delay" *always overlaps* with any periods of "A delay" for the purposes of applying § 154(b)(2)(A).

The problem with the PTO's construction is that it considers the application *delayed* under § 154(b)(1)(B) during the period *before it has been delayed*. That construction cannot be squared with the language of § 154(b)(1)(B), which applies "if the issue of an original patent is *delayed* due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." (Emphasis added.) "B delay" begins when the PTO has failed to issue a patent within three years, not before.

The PTO's interpretation appears to be driven by Congress's admonition that any term extension "not ex-

ceed the actual number of days the issuance of the patent was delayed," and by the PTO's view that "A delays" during the first three years of an applications' pendency inevitably lead to "B delays" in later years. Thus, as the PTO sees it, if plaintiffs' construction is adopted, one cause of delay will be counted twice: once because the PTO has failed to meet an administrative deadline, and again because that failure has pushed back the entire processing of the application into the "B period." Indeed, in the example set forth above, plaintiffs' calendar-day construction does result in a total effective patent term of 18 years under the (B) guarantee, so that -- again from the PTO's viewpoint -- the applicant is not "compensated" for the PTO's administrative delay, he is benefited by it.

But if subsection (B) had been intended to guarantee a 17-year patent term and *no more*, it could easily have been written that way. It is true that the legislative context -- as distinct from the legislative history -- suggests that Congress may have intended to use subsection (B) to guarantee the 17-year term provided before GATT. But it chose to write a "[g]uarantee of no more than 3-year application pendency," 35 U.S.C. § 154(b)(1)(B), not merely a guarantee of 17 effective years of patent term, and do so using language separating that guarantee from a different promise of prompt administration in subsection (A). The PTO's efforts to prevent windfall extensions may be reasonable -- they may even be consistent with Congress's intent -- but its interpretation must square with Congress's words. If the outcome commanded by that text is an unintended result, the problem is for Congress to remedy, not the agency.

JAMES ROBERTSON

United States District Judge